Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 1. General Provisions

§101. Scope

A. Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.

B. Attention is directed to the fact that state regulation of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the U.S. Nuclear Regulatory Commission and to Parts 40 and 150 of the U.S. Nuclear Regulatory Commission's regulations (10 CFR Parts 40 and 150).

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 27:1225 (August 2001).

§102. Definitions and Abbreviations

As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain chapter may be found in that Chapter.

A_1—the maximum activity of special form radioactive material permitted in a Type A package.

A_2—the maximum activity of radioactive material, other than special form, LSA, and SCO material, permitted in a Type A package. These values are either listed in, or may be derived in accordance with the procedure prescribed in, Appendix A of 10 CFR Part 71.

Absorbed Dose—the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

Accelerator-Produced Material—Repealed (February 2014).

Accelerator-Produced Radioactive Material—any material made radioactive by a particle accelerator.

Act—the Louisiana Environmental Quality Act, (R.S. 30:2001 et seq).

Activity—the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

Address of Use—the building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

Administrative Authority—the Secretary of the Department of Environmental Quality or his designee or the appropriate assistant secretary or his designee.

Adult—an individual 18 or more years of age.

Agreement State—any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under Subsection 274.b of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

Airborne Radioactive Material—any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Airborne Radioactivity Area—a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

1. in excess of the derived air concentrations (DACs) specified in LAC 33:XV.499.Appendix B, Table I of these regulations; or

2. to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

Alert—events that may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by off-site response organizations to protect persons off-site.

Area of Use—a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.

As Low As Is Reasonably Achievable (ALARA)—making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

5. No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in 10 CFR 30.71 schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this Chapter.

C. Exempt Items

1. Certain Items Containing Byproduct Material. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Except for persons who apply byproduct material to, or persons who incorporate byproduct material into, the following products, or persons who initially transfer for sale or distribution the following products containing byproduct material, any person is exempt from these regulations to the extent that he or she receives, possesses, uses, transfers, owns, or acquires the following products:

a. timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified levels of radiation:

i. 25 millicuries (925 MBq) of tritium per timepiece;

ii. 5 millicuries (185 MBq) of tritium per hand;

iii. 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial);

iv. 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;

v. 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand;

vi. 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

vii. the levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a). for wrist watches, 0.1 millirad (1 μGy) per hour at 10 centimeters from any surface;

(b). for pocket watches, 0.1 millirad (1 μGy) per hour at 1 centimeter from any surface; and

(c). for any other timepiece, 0.2 millirad (2 μGy) per hour at 10 centimeters from any surface;

viii. 1 microcurie (0.037 MBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007;

b. devices such as:

i. static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcurie (18.5 MBq) of polonium-210 per device;

ii. ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device;

iii. such devices authorized before October 23, 2012, for use under the general license then provided in 10 CFR 31.3 and equivalent regulations of agreement states and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Nuclear Regulatory Commission;

c. precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007;

d. marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007;

e. ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires;

f. electron tubes, provided that no tube contains more than one of the following specified quantities of byproduct material:

i. 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

ii. 1 microcurie of cobalt-60;

iii. 5 microcuries of nickel-63;

iv. 30 microcuries of krypton-85;

v. 5 microcuries of cesium-137;

vi. 30 microcuries of promethium-147; and

vii. provided further, that the levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber; and

viii. for purposes of this Subsection, *electron tubes* include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other

completely sealed tube that is designed to conduct or control electrical currents;

g. ionizing radiation measuring instruments containing, for the purposes of internal calibration or standardization, one or more sources of byproduct material, provided that:

i. each source contains no more than one exempt quantity set forth in Schedule B of this Chapter;

ii. each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides, and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B of this Chapter, provided that the sum of such fractions shall not exceed unity; and

iii. for purposes of this Section, 0.05 microcurie of americium-241 is considered an exempt quantity under Schedule B of this Chapter.

2. Self-Luminous Products Containing Byproduct Material

a. Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from the requirements for a license set forth in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.22, which license authorizes the initial transfer of the product for use under this Subparagraph. Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under this Subparagraph, shall apply for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 10 CFR 32.210. The exemption in this Subparagraph does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

b. Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie of radium-226 that were acquired prior to April 20, 1977.

3. Gas and Aerosol Detectors Containing Byproduct Material

a. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.26, which license authorizes the initial transfer of the product for use under this Section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a state under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

b. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under LAC 33:XV.304.C.3.a shall apply for a license under 10 CFR 32.26 and for a certificate of registration in accordance with 10 CFR 32.210.

c. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a licensing state shall be considered exempt under LAC 33:XV.304.C.3.a, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that the device meets the requirements of LAC 33:XV.328.C.

4. Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use for Humans

a. Except as provided in Subparagraphs C. 4.b and c of this Section, any person is exempt from the requirements for a license set forth in these regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1μCi) carbon-14 urea each (allowing for nominal variation that may occur during the manufacturing process), for "in vivo" diagnostic use for humans.

b. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license in accordance with LAC 33:XV.Chapters 3 and 7.

c. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license in accordance with LAC 33:XV.328.K.

d. Nothing in this Section relieves persons from complying with applicable FDA, other federal, and state requirements governing receipt, administration, and use of drugs.

5. Certain Industrial Devices

a. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for

a license set forth in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under this Section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

b. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under Subparagraph a of this Section, shall apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with LAC 33:XV.361.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq., and 2104.B.(1).

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Subchapter B. Licenses

§320. Types of Licenses

A. Licenses for radioactive materials are of two types: general and specific.

1. General licenses provided in this Chapter are effective without the filing of application with the Office of Environmental Compliance or the issuance of licensing documents to the particular persons, although the filing of certain information with the Office of Environmental Compliance may be required by the particular general license. The general licensee is subject to all other applicable portions of these regulations and to any limitations of the general license.

2. Specific licenses require the submission of an application to the Office of Environmental Compliance and the issuance of a licensing document by the administrative authority. The licensee is subject to all applicable portions of these regulations as well as to any limitations specified in the licensing document. The licensee shall notify the Office of Environmental Compliance in writing before making any change that would render the information contained in the application for license no longer accurate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2566 (November 2000), LR 29:1816 (September 2003), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2524 (October 2005), LR 33:2176 (October 2007).

Subchapter C. General Licenses

§321. General Licenses: Source Material

A. A general license is hereby issued authorizing use and transfer of not more than 15 pounds (6.8 kilograms) of source material at any one time by commercial and industrial firms, and research, educational, and medical institutions for research, development, educational, operational, or commercial purposes; and provided further that no such person shall, pursuant to this general license, receive more than a total of 150 pounds of source material in any one calendar year.

B. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in LAC 33:XV.321.A are exempt from the provisions of Chapters 4 and 10 of these regulations to the extent that such receipt, possession, use, or transfer is within the terms of such general license, provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this Chapter.

C. Persons who receive, possess, use, or transfer source material pursuant to the general license in LAC 33:XV.32l.A.1 are prohibited from administering source material or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the department in a specific license.

D. A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

E. Depleted Uranium in Industrial Products and Devices

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of LAC 33:XV.321.E.2, 3, 4, and 5, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in LAC 33:XV.321.E.1 applies only to industrial products or devices that have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to LAC 33:XV.328.M or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state that authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

3. Depleted Uranium

a. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established

by Paragraph E.1 of this Section shall file Form DRC-21, "General License Certificate—Use of Depleted Uranium Under General License," with the Office of Environmental Compliance. Form DRC-21 will be furnished by the Office of Environmental Compliance upon written request. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on Form DRC-2l the following information and such other information as may be required by that form:

i. name and address of the general licensee;

ii. a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in LAC 33:XV.321.E.1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

iii. name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in LAC 33:XV.321.E.3.a.ii.

b. The licensee possessing or using depleted uranium under the general license established by Paragraph E.1 of this Section shall report in writing to the Office of Environmental Compliance any changes in information furnished by him in Form DRC-21, "General License Certificate—Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by LAC 33:XV.321.E.1:

a. shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

b. shall not abandon such depleted uranium;

c. shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of LAC 33:XV.340. In the case where the transferee receives the depleted uranium pursuant to the general license established by LAC 33:XV.321.E.1, the transferor shall furnish the transferee a copy of this regulation and a copy of Form DRC-2l. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to LAC 33:XV.321.E.1, the transferor shall furnish the transferee a copy of this regulation and a copy of FORM DRC-21 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in this regulation;

d. within 30 days of any transfer, shall report in writing to the Office of Environmental Compliance the name and address of the person receiving the depleted uranium pursuant to such transfer; and

e. shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 110.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by LAC 33:XV.321.E.1 is exempt from the requirements of Chapters 4 and 10 of these regulations with respect to the depleted uranium covered by that general license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2567 (November 2000), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2524 (October 2005), LR 33:2177 (October 2007).

§322. General Licenses: Radioactive Material Other Than Source Material

A. Reserved.

B. Antiquities, Timepieces, and Luminous Devices

1. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of Paragraphs B.1-4 of this Section, radium-226 contained in the following products manufactured prior to November 30, 2007:

a. Antiquities Originally Intended for Use by the General Public. For the purposes of this Paragraph, antiquities are products originally intended for use by the general public and distributed in the late nineteenth and twentieth centuries, (e.g., radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads);

b. intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces;

c. luminous items installed in air, marine, or land vehicles;

d. all other luminous products, provided that no more than 100 items are used or stored at the same location at any one time; and

e. small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. [For the purposes of this Paragraph, small radium sources are: discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (e.g., cloud chambers and

c. identification of the individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in LAC 33:XV.763.K or 10 CFR 32.72(b)(2); and

d. information on the PET drugs to be noncommercially transferred to members of its consortium, including the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and the storage of the radioactive drugs by medical use licensees.

2. Except as provided in Paragraphs D.3, 4, and 5 of this Section, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source shall:

a. identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210, with an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a state under provisions comparable to 10 CFR 32.210; or

b. contain the information identified in 10 CFR 32.210(c).

3. For sources or devices manufactured before October 23, 2012, that are not registered with the NRC under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the application shall include:

a. all available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

b. sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information shall include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

4. For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply the manufacturer, model number, radionuclide, and quantity.

5. If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

E. In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the department, provided such references are clear and specific.

F. Applications and documents submitted to the department shall be available for public inspection unless the administrative authority makes a written determination of confidentiality in accordance with LAC 33:I.Chapter 5.

G. If the department determines that any material should not be afforded confidentiality, a written denial of the request will be issued to the requestor in accordance with LAC 33:I.Chapter 5.

H. Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in LAC 33:XV.399.Appendix C (Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release) must contain either:

1. an evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

2. an emergency plan for responding to a release of radioactive material.

I. One or more of the following factors may be used to support an evaluation submitted under LAC 33:XV.324.H.1:

1. the radioactive material is physically separated so that only a portion could be involved in an accident;

2. all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

3. the release fraction in the respirable size range would be lower than the release fraction shown in LAC 33:XV.399.Appendix C due to the chemical or physical form of the material;

4. the solubility of the radioactive material would reduce the dose received;

5. facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in LAC 33:XV.399.Appendix C;

6. operating restrictions or procedures would prevent a release fraction as large as that shown in LAC 33:XV.399.Appendix C; or

7. other factors appropriate for the specific facility.

J. An emergency plan for responding to a release of radioactive material submitted under LAC 33:XV.324.H.2 must include the following information:

1. Facility Description. A brief description of the licensee's facility and area near the site;

2. Types of Accidents. An identification of each type of radioactive materials accident for which protective actions may be needed;

from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in the table in LAC 33:XV.410.A.

iii. Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses.

(a). whole body, head and trunk active blood-forming organs, gonads, or lens of eye	15 rems
(b). hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than 1 square centimeter	200 rems
(c). other organs	50 rems

c. Each device bears a durable, legible, clearly visible label or labels approved by the department that contain in a clearly identified and separate statement:

i. instructions and precautions necessary to assure safe installation, operation and servicing of the device (document such as operating and service manuals may be identified in the label and used to provide this information);

ii. the requirement, or lack of requirement, for testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

iii. the information called for in the following statement in the same or substantially similar form:

(a). the receipt, possession, use, and transfer of this device Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement or the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

(Name of Manufacturer or Distributor)

The model, serial number, and name of manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(b). the receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL

_____

(Name of Manufacturer or Distributor)

d. each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words "Caution—Radioactive Material," the radiation symbol described in LAC 33:XV.450, and the name of the manufacturer or initial distributor;

e. each device meeting the criteria of LAC 33:XV.322.D.3.l bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing, if separable, or to the device if the source housing is not separable, that includes the words "Caution—Radioactive Material" and, if practicable, the radiation symbol described in LAC 33:XV.450.

f. The device has been registered in the Sealed Source and Device Registry.

2. In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material, or for both, the applicant shall include in his or her application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the department will consider information that includes, but is not limited to:

a. primary containment (source capsule);

b. protection of primary containment;

c. method of sealing containment;

d. containment construction materials;

e. form of contained radioactive material;

f. maximum temperature withstood during prototype tests;

g. maximum pressure withstood during prototype tests;

h. maximum quantity of contained radioactive material;

i. radiotoxicity of contained radioactive material; and

j. operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general licensee under LAC 33:XV.322.D, or under equivalent regulations of the U.S. Nuclear Regulatory Commission or of any other agreement state or licensing state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he or she shall include

d. Maintain all information concerning transfers and receipts of devices that supports the reports required by this Paragraph. This information and the reports must be maintained for a period of three years following the date of the recorded event.

e. Report to the Office of Environmental Compliance all transfers of such devices to persons for use under the general license in LAC 33:XV.322.D. Such reports must be maintained for a period of three years following the date of the recorded event and shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under LAC 33:XV.322.D during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter.

f. For all transfers out of Louisiana, the distributor shall make reports prescribed in this Paragraph as follows.

i. Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR 31.5.

ii. Report to the responsible state agency all transfers of devices manufactured and distributed in accordance with this Subsection for use under a general license in that state's regulations equivalent to LAC 33:XV.322.D.

iii. Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such device is transferred to the person generally licensed.

iv. If no transfers have been made to the U.S. Nuclear Regulatory Commission's licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

v. If no transfers have been made to persons generally licensed within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of the agency.

g. Keep records showing the name, address, and the point of contact for each general licensee to whom he or she directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in LAC 33:XV.322.D, or equivalent regulations of the U.S. Nuclear Regulatory Commission or any other agreement state or licensing state. The records must show the date of each transfer, the isotope and the quantity of radioactive material in each device transferred, the identity of any intermediate person, and compliance with the reporting requirements of this Paragraph.

E. Special Requirements for the Manufacture, Assembly, Repair, or Initial Transfer of Luminous Safety Devices for Use in Aircraft

1. An application for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under LAC 33:XV.322.E, will be approved subject to the following conditions:

a. the applicant satisfies the general requirements specified in LAC 33:XV.325; and

b. the applicant satisfies the requirements of 10 CFR 32.53, 32.54, 32.55, and 32.56 or their equivalent.

F. Special Requirements for License to Manufacture or Initially Transfer Calibration or Reference Sources Containing Americium-241 or Radium-226 for Distribution to Persons Generally Licensed under LAC 33:XV.322.G

1. An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under LAC 33:XV.322.G, will be approved subject to the following conditions:

a. the applicant satisfies the general requirement of LAC 33:XV.325; and

b. the applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

i. chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

ii. details of construction and design;

iii. details of the method of incorporation and binding of the americium-241or radium-226 in the source;

iv. procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

v. details of quality control procedures to be followed in the manufacture of the source;

vi. description of labeling to be affixed to the source or the storage container for the source; and

vii any additional information, including experimental studies and test, required by the department to facilitate a determination of the safety of the source.

c. Each source shall contain no more than 5 microcuries of americium-241 or radium-226.

d. The department determines, with respect to any type of source containing more than 0.005 microcurie of americium-241or radium-226, that:

i. the method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

ii. the source has been subjected to and has satisfactorily passed appropriate tests required by Subparagraph F.1.e of this Section.

e. The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

i. the initial quantity of radioactive material deposited on each source is measured by direct counting of the source;

ii. the sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion;

iii. the sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in Clause F.1.e.iv of this Section; and

iv. source designs are rejected for which the following has been detected for any unit: removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

2. Each person licensed to manufacture or initially transfer calibration or reference sources shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:[1]

a. the receipt, possession, use, and transfer of this source, Model ____, Serial No. ____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226).

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of Manufacturer or Initial Transferor)

3. Each person licensed to manufacturer or initially transfer calibration or reference sources shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under LAC 33:XV.322.G or equivalent regulations of the U. S. Nuclear Regulatory Commission, licensing state or any other agreement state. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this Paragraph, the source shall be rejected and shall not be transferred to a general licensee under LAC 33:XV.322.G or equivalent regulations of the U. S. Nuclear Regulatory Commission, licensing state, or any other agreement state.

G. Reserved.

H. Licensing the Manufacture and Distribution of Byproduct Material for Certain In Vitro Clinical or Laboratory Testing under a General License

1. An application for a specific license to manufacture or distribute byproduct material for use under an appropriate general license or equivalent will be approved subject to the following conditions:

a. the applicant satisfies the general requirements specified in LAC 33:XV.325;

b. the byproduct material is to be prepared for distribution in prepackaged units of:

i. iodine-125 in units not exceeding 0.37 megabecquerel (10 microcuries) each;

ii. iodine-131 in units not exceeding 0.37 megabecquerel (10 microcuries) each;

iii. carbon-14 in units not exceeding 0.37 megabequerel (10 microcuries) each;

iv. hydrogen-3 (tritium) in units not exceeding 1.85 megabecuerels (50 microcuries) each;

v. iron-59 in units not exceeding 0.74 megabecquerel (20 microcuries) each;

vi. cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each;

vii. selenium-75 in units not exceeding 0.37 megabecquerel (10 microcuries) each; or

viii. mock iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; and

c. Each prepackaged unit bears a durable, clearly visible label:

i. identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (10 microcuries) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 megabecquerels (50 microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (20 microcuries) of iron-59; or mock iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; and

ii. displaying the radiation caution symbol described in LAC 33:XV.450.A and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals".

d. One of the following statements, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

i. This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license, or equivalent license, of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____
(Name of Manufacturer)

ii. This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license, or equivalent license, of a licensing state.

_____
(Name of Manufacturer)

2. The label affixed to the unit, or the leaflet or brochure that accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in LAC 33:XV.431.

I. Licensing the Manufacture and Distribution of Ice-Detection Devices

1. An application for a specific license to manufacture and distribute ice-detection devices to persons generally licensed under LAC 33:XV.322.J will be approved subject to the following conditions:

a. the applicant satisfies the general requirements of LAC 33:XV.325; and

b. the criteria of 10 CFR 32.61 and 32.62 are met.

J. Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Byproduct Material for Medical Use under LAC 33:XV.Chapter 7

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized in accordance with LAC 33:XV.Chapter 7 shall be approved if the following conditions are met:

a. the applicant satisfies the general requirements for the issuance of specific licenses specified in LAC 33:XV.325;

b. the applicant submits to the Office of Environmental Compliance evidence that the applicant is at least one of the following:

i. registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

ii. registered or licensed with a state agency as a drug manufacturer;

iii. licensed as a pharmacy by the Louisiana Board of Pharmacy;

iv. operating as a nuclear pharmacy within a federal medical institution; or

v. a positron emission tomography (PET) drug production facility licensed or registered with a state agency.

c. the applicant submits to the Office of Environmental Compliance information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the radioactive material that is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

d. the labeling meets the following criteria:

i. the label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. For radioactive

c. the applicant provides evidence that each capsule contains 37 kBq (1μCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

d. the carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this Section), or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

e. the carbon-14 urea is in the form of a capsule, is identified as radioactive, and is to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution. The capsule shall meet the following conditions:

i. the immediate container of the capsule(s) bears a durable, legible label that:

(a). identifies the radioisotope, the physical and chemical form, and the quantity of radioactivity of each capsule at a specific date; and

(b). bears the words "Radioactive Material";

ii. in addition to the labeling information required by Clause K.1.e.i of this Section, an accompanying brochure or the label affixed to the immediate container also:

(a). states that the contents are exempt from department licensing requirements; and

(b). bears the words "Radioactive Material. for "In Vivo" Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Shall Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals or into Products Manufactured for Commercial Distribution. This Material May Be Disposed of in Ordinary Trash"; and

f. the applicant submits copies of prototype labels and brochures and the department approves these labels and brochures.

2. Nothing in this Section relieves the licensee from complying with applicable FDA, other federal, and state requirements governing drugs.

L. Licensing the Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use

1. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Chapter 7 for use as a calibration, transmission, or reference source or for the uses listed in LAC 33:XV.739, 741, and 747 of these regulations will be approved if the following conditions are met.

a. The applicant satisfies the general requirements in LAC 33:XV.325.

b. The applicant submits to the Office of Environmental Compliance sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

i. the radioactive material contained, its chemical and physical form, and the amount;

ii. details of design and construction of the source or device;

iii. procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use;

iv. for devices containing radioactive material, the radiation profile of a prototype device;

v. details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

vi. procedures and standards for calibrating sources and devices;

vii. legend and methods for labeling sources and devices as to their radioactive content; and

viii. instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device, provided that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure referenced on the label.

c. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, date of assay, and a statement that the source or device is licensed by the administrative authority for distribution to persons licensed pursuant to Chapter 7 and LAC 33:XV.739 and 741, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, any other agreement state, or a licensing state, provided that such labeling for sources that do not require long-term storage (e.g., gold-198 seeds) may be on a leaflet or brochure that accompanies the source.

d. the source or device has been registered in the Sealed Source and Device Registry.

2. Intervals for Leakage Tests

a. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he or she shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

§350. Modification and Revocation of Licenses

A. The terms and conditions of all licenses shall be subject to amendment, revision, or modification, or the license may be suspended or revoked by reason of amendments to the act or by reason of rules, regulations, and orders issued by the administrative authority.

B. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the act or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the administrative authority to refuse to grant a license on an original application, or for violation of, or failure to observe, any of the terms and conditions of the act, or of the license, or of any rule, regulation, or order of the administrative authority. Whether a false statement is material shall be determined by the administrative authority.

C. Except in cases of willfulness or those in which the public welfare, interest, or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the licensee in writing, and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992).

§351. Financial Assurance Arrangements

A. Issuance of a license shall be dependent upon satisfactory evidence of financial assurance to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of these regulations. Pursuant to R.S. 30:2114 of the Louisiana Radiation Protection and Radiation Control Law, and as otherwise provided, financial assurance arrangements for site decontamination, mitigation, liability, and/or decommissioning may consist of financial assurance bonds, cash deposits, personal bonds, letters or lines of credit, or any combination of the above for the categories of licenses listed in LAC 33:XV.351.D. Determination of satisfactory financial assurance arrangements shall be subject to the following conditions:

1. the amount of funds to be ensured by such assurance arrangements shall be based on the quantity of radioactive material of half-life greater than 120 days that the licensee is authorized to use and possess;

2. self-insurance, or any arrangement that essentially constitutes self-insurance, will not satisfy the financial assurance requirement since this provides no further assurance than being without insurance.

B. The arrangements required in LAC 33:XV.351.A shall be established prior to issuance of the license to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility.

C. Amendments to licenses in effect on the effective date of this regulation may be issued providing that the required financial assurance arrangements are established within 90 days after the effective date of LAC 33:XV.351.

D. The following licensees are required to make financial assurance arrangements:

1. major processors;

2. waste-handling licensees;

3. all others except licensees exempt in accordance with LAC 33:XV.399.Appendix A; and

4. any other licensee that the department determines to have the potential to default, abandon, or otherwise cause liabilities that would endanger public health and safety.

E. The department may reevaluate, at any time, the adequacy of an existing financial assurance arrangement and may require an adjustment by either increasing or decreasing the amount of the financial assurance arrangement required.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2573 (November 2000), LR 27:1228 (August 2001), amended by the Office of Environmental Assessment, LR 31:45 (January 2005).

§361. Registration of Product Information

A. Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the department for evaluation of radiation safety information about its product and for its registration.

B. The request for review must be sent by an appropriate method to the Office of Environmental Compliance.

C. The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses, and leak testing. For a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

D. The department normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the department formulates reasonable standards and criteria with the help of the manufacturer or distributor. The department shall use criteria and standards sufficient to ensure that the radiation safety properties of the

device or sealed source are adequate to protect health and minimize danger to life and property. LAC 33:XV.Chapter 3 includes: specific criteria that apply to certain exempt products; specific criteria applicable to certain generally licensed devices; and specific provisions that apply to certain specifically licensed items.

E. After completion of the evaluation, the department issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

F. The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

1. the statements and representations, including quality control program, contained in the request; and

2. the provisions of the registration certificate.

G. Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

1. calibration and reference sources containing no more than:

a. 37 MBq (1 mCi) for beta and/or gamma emitting radionuclides; or

b. 0.37 MBq (10 µCi) for alpha emitting radionuclides; or

2. the intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

a. the intended recipients are licensed under LAC 33:XV.327 or comparable provisions of the U. S. Nuclear Regulatory Commission or an agreement state; or

b. the recipients are authorized for research and development; or

c. the sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

H. After the certificate is issued, the department may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the department will complete its evaluation in accordance with criteria specified in this Section. The department may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

I. Inactivation of Certificates of Registration of Sealed Sources and Devices

1. A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the department shall request inactivation of the registration certificate. Such a request shall be made to the Office of Environmental Compliance and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

2. If a distribution license is to be terminated in accordance with LAC 33:XV.332, the licensee shall request inactivation of its registration certificates associated with that distribution license before the department will terminate the license. Such a request for inactivation of certificate(s) shall indicate that the license is being terminated and include the associated specific license number.

3. A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices shall be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

J. Serialization of Nationally Tracked Sources. Each licensee who manufactures a nationally tracked source after February 6, 2007, shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, LR 31:45 (January 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2528 (October 2005), LR 33:1017 (June 2007), LR 33:2180 (October 2007), amended by the Office of the Secretary, Legal Division, LR 41:1278 (July 2015).

Subchapter E. Reciprocity

§390. Reciprocal Recognition of Licenses

A. Subject to these regulations, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, any other agreement state, or any licensing state and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state, except in areas of exclusive federal jurisdiction,